UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

KERRI DOLAN and DEAN DOLAN, Plaintiffs, v. BOSTON SCIENTIFIC CORP. Defendant.	Court File No.: 0:20-cv-1827 **COMPLAINT** **DEMAND FOR JURY TRIAL**

TO: ABOVE NAMED DEFENDANT AND THEIR ATTORNEYS

Plaintiffs, by and through counsel, allege on personal knowledge as to themselves, and on information and belief as to all other matters, as follows against Defendant Boston Scientific Corporation (hereinafter "Boston Scientific" or "BSC"):

I. NATURE OF THESE ACTIONS

1. Plaintiffs seek compensation for injuries resulting from use of Defendant's Solyx Single-Incision Sling System, which Defendants designed, manufactured, marketed, distributed, packaged, and sold.

II. PLAINTIFFS

2. Plaintiff Kerri Dolan is and was at all relevant times a resident of Otter Tail County, Minnesota.

3. Plaintiff Dean Dolan is and was at all relevant times the lawful husband of Plaintiff Kerri Dolan.

III. DEFENDANTS

4. Defendant Boston Scientific Corp. is and was at all relevant times a Delaware Corporation with its principal place of business located at 300 Boston Scientific Way, Marlborough, Massachusetts 01752.

5. At all relevant times herein mentioned, Defendant Boston Scientific conducted regular and sustained business in Minnesota by marketing, distributing and selling its products in Minnesota. Boston Scientific also has two manufacturing facilities in the State of Minnesota, located in Arden Hills and in Maple Grove. All acts and omissions of Boston Scientific as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownerships.

6. The product known as the Solyx Sling System (hereinafter "Solyx Sling" or "Solyx"), as well as any variations of this product and any unnamed BSC Pelvic Mesh Products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation and the Pelvic Mesh Products designed and sold for similar purposes by the defendant listed below, are collectively referenced herein as "Defendant's Pelvic Mesh Products" or "the Products."

7. The Defendant had a legal duty to ensure the safety and effectiveness of its Pelvic Mesh Products by conducting adequate and well-controlled studies on its Products prior to marketing. The Defendant deliberately chose to manipulate the only studies that were conducted on their Products, and by so doing, provided doctors and patients with false and misleading information about the safety and effectiveness of their Pelvic Mesh Products. Furthermore, the Defendant made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of the Pelvic Mesh Products.

8. At all times material to this action, Defendant has designed, patented, manufactured, labeled, marketed, and sold and distributed a line of Pelvic Mesh Products. These Products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ

prolapse. These Products share common design elements and common defects. Additionally, each of these Products were cleared for sale in the U.S. after the Defendant made assertions to the Food and Drug Administration ("FDA") of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

9. At all times alleged herein, the Defendant includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

JURISDICTION AND VENUE

10. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiffs and the Defendants, and because Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs.

11. Venue is proper as Plaintiff was implanted with the defective device and was injured in and received treatment in the State of Minnesota.

RELEVANT FACTS

IV. THE SOLYX SINGLE INCISION SLING SYSTEM

12. Boston Scientific's Solyx System is a mid-urethral mesh sling "intended for use as a sub-urethral sling for the treatment of stress incontinence resulting from urethral hyper-mobility and/or intrinsic sphincter deficiency."[1]

[1] *See* http://web.archive.org/save/https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/sites/pfi/physicianResources/vac/mid_urethral_slings_vac_pack.pdf.

13. Boston Scientific designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed Solyx sling products, which are delineated below. These products were designed primarily for the purposes of treating stress urinary incontinence.

14. At all material times hereto, Defendant engaged in the developing, inspecting, testing, assembling, designing, licensing, labeling, manufacturing, distributing, packaging, supplying, marketing, advertising, and/or selling, either directly or indirectly through third parties or related entities, transvaginal placed mesh devices for the treatment of incontinence and pelvic organ prolapse.

15. The Defendant knew, or should have known, that the transvaginal placed mesh devices were defective and not safe and/or effective as originally developed, inspected, tested, assembled, designed, licensed, labeled, manufactured, distributed, packaged, supplied, marketed, advertised and/or sold.

16. Many of Defendant's Pelvic Mesh Products, including the Solyx Sling, contain non-absorbable synthetic, monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that this material, as implanted in the Kerri Dolan, is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Defendant's Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

17. Furthermore, Defendant's Pelvic Mesh Products cause hyper-inflammatory responses leading to problems including chronic pain and fibrosis. Defendant's polypropylene mesh Products disintegrate after implantation in the female pelvis. They harden in the body. When polypropylene mesh is inserted in the female body according to the manufacturers'

instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

18. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Boston Scientific, among other device companies, began to modify the mesh used in hernia repair to be used as products specifically intended to correct pelvic organ prolapse and/or SUI. Boston Scientific sold pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Pelvic Mesh Products manufactured by Boston Scientific are regulated by the U.S. Food and Drug Administration (FDA) and until 2016 were considered Class II medical devices.[2],[3]

19. Defendant sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices in commercial distribution prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Boston Scientific with regard to the Pelvic Mesh Devices prior to placing them on the market.

20. Between approximately 2005 and 2007, the Food and Drug Administration (FDA), received reports of over 1,000 adverse events associated with transvaginally placed mesh devices.

[2] In 2016, the FDA reclassified surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse as Class III (high risk) medical devices.
[3] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants.

21. Between approximately 2008 and 2010, the FDA received over 2,800 reports of adverse events involving individuals who had transvaginally placed mesh devices. The reported complications from these devices included, but were not limited to, mesh erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation and urinary problems. Many of these complications required additional extensive surgical intervention and treatment.

22. Defendant's Solyx device contains monofilament polypropylene mesh. The Pelvic Mesh Device was designed and intended to be permanently implanted into the human body. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the devices. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

23. Boston Scientific used Marlex® HGX-030-01 Polypropylene Homopolymer resin in its transvaginal mesh kits, both pelvic organ prolapse kits and sling systems. The Marlex® resin was manufactured by Phillips Sumika Polypropylene Company, ("Phillips") a joint venture between Chevron Phillips Chemical Company, LP, and Sumitomo Chemical.

24. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips issued revised Material Safety Data Sheets ("MSDS") for Marlex polypropylene. Boston Scientific was aware of the Marlex MSDS at all relevant times, including when it manufactured and marketed its Pelvic Mesh Devices to the medical community, including Plaintiff's physicians.

25. The Marlex MSDS expressly prohibits use of the material for permanent human implantation:

> "MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.
>
> DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.
>
> CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES."

26. On October 1, 2004, Phillips Sumika Polypropylene Company (PSPC) entered a one-year stand-alone indemnification/insurance agreement which waived the company's liability for Boston Scientific's decision to use the polypropylene material in medical applications. That agreement included the following language for Boston Scientific's use of the resin material in its transvaginal mesh products:

> BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT, BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE SAFETY AND SUITABILITY OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

27. The 2004 Indemnity Agreement placed the burden on Boston Scientific to conduct any and all necessary testing to ensure that the product they marketed with Marlex resin was safe for its intended use.

28. Boston Scientific performed no long-term safety studies on the dangers associated with the permanent implantation of its Pelvic Mesh Devices.

29. Subsequent to this 2004 indemnity agreement, in September of 2005, Phillips decided not to renew its contract with Boston Scientific, because the resin was not intended for use in permanent implant devices. Per the terms of the 2004 contract between the two companies, Boston Scientific decided to exercise a right it held to make a "last-time" buyout before the contract was terminated. In 2005, Boston Scientific purchased 4,000 pounds of Marlex® HGX-030-01, the equivalent of a 10-year supply.

30. Synthetic materials like polypropylene are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh. Notably, the polypropylene MSDS specifies that polypropylene may react with strong oxidizing agents. Despite the known warnings and complications, Boston Scientific utilized Marlex that had never been qualified by the supplier for permanent human implantation for a medical application that was disallowed according to the Material Safety Data Sheet (MSDS) in its manufacture of the Pelvic Mesh Devices.

31. The polypropylene mesh used by Boston Scientific for its Pelvic Mesh Devices also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on their anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at

rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

32. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in Defendant's Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

V. FDA REGULATORY ACTION

33. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

34. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

35. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non-mesh repair." In the July 13, 2011, Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete

removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendant and was not disclosed in any manner.

36. In September 2011, FDA convened a public meeting of the Obstetrics and Gynecology Devices Panel to discuss the benefits and risks of pelvic mesh. As a result, FDA subsequently issued orders to 34 manufacturers, requiring them to conduct postmarket surveillance studies for transvaginal repair of pelvic organ prolapse (POP). Most manufacturers elected to stop marketing surgical mesh for transvaginal repair of POP following the issuance of these orders from the FDA.[4]

37. In January 2016, FDA reclassified transvaginal mesh devices used for POP as Class III devices (the highest risk class), which requires premarket approval.[5]

38. On February 12, 2019, the FDA convened an advisory committee meeting to share available evidence and seek opinions on evaluating the risks and benefits of mesh used for POP repair.[6]

39. Subsequently on April 16, 2019, FDA ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair or pelvic organ prolapse to stop selling and distributing their products in the United States immediately.[7]

[4] https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal.
[5] https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal.
[6] https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal.
[7] https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal.

VI. IN SPITE OF THEIR KNOWLEDGE TO THE CONTRARY, BOSTON SCIENTIFIC CONTINUES TO MARKET ITS PRODUCTS TO PHYSICIANS AND PATIENTS AS SAFE AND EFFECTIVE

40. Notwithstanding the above, the Defendant continued to aggressively market and advertise transvaginally placed mesh devices, including the Solyx Sling, as safe and effective. The Defendant did not provide adequate warnings to doctors and the health care community about the increased risk of serious adverse events associated with transvaginally placed mesh devices. The Defendant neither halted the sales of transvaginally placed mesh devices nor warned medical professionals of their dangers.

41. Instead, the Defendant expressly warranted that its transvaginally placed mesh devices were safe and fit for use by consumers, that they were of merchantable quality, and that they were adequately tested and fit for their intended use, even though they were not safe and had numerous side effects, many of which Defendant did not accurately warn about.

42. Defendant marketed and sold the Pelvic Mesh Products through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but were not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers.

43. Defendant also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of these products. The Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

44. Contrary to Defendant's representations and marketing, Defendant's Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries,

conditions, and damage to a significant number of women, including Plaintiff Kerri Dolan. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results;

b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade;

e. the use and design of anchors in the Pelvic Mesh Products that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the trocars (devices used to insert the Pelvic Mesh Products into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

45. Defendant suppressed information about the defective nature of its Pelvic Mesh Products and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff's physicians. As a result, Defendant actively and intentionally misled and continues to mislead physicians and the medical community into

believing that Defendant's Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

46. Defendant failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of its Pelvic Mesh Products.

47. Defendant failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

48. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse have existed at all times relevant to this matter.

49. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

50. Defendant provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of these products.

51. Defendant's Pelvic Mesh Products implanted into Plaintiff Kerri Dolan were in the same or substantially similar condition as they were when they left the possession of Defendant, as well as being in the condition directed by and expected by Defendant.

52. Plaintiff Kerri Dolan and her physicians foreseeably used and implanted Defendant's Pelvic Mesh Products, and did not misuse or alter these products in an unforeseeable manner.

53. The injuries, conditions, and complications suffered by women who have been implanted with Defendant's Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain

during sexual intercourse), blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

54. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in Defendant's Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

PLAINTIFF'S INJURIES

55. On August 9, 2018, Ms. Dolan underwent surgery, wherein her surgeon implanted the Solyx sling and anchored it to the obturator membrane bilaterally.

56. On January 28, 2019, approximately six months after the implantation of the Solyx device, Ms. Dolan presented to a urologist, after being referred by her primary doctor, for the evaluation of pelvic pain. Ms. Dolan's doctor ultimately recommended removal of the sling.

57. On April 19, 2019, Ms. Dolan underwent surgical removal of the Boston Scientific Solynx Sling from her posterior vaginal wall. Unfortunately, Ms. Dolan's surgeon was unable to remove the entire device due at least in part to excessive scarring, and the operative report notes that the device was not in the correct anatomical position. The explanting surgeon described extending the mucosal defect at the mesh exposure with Metzenbaum scissors to expose the sling at the "right periurethral sulcus."

58. Following this procedure, Ms. Dolan continued to experience severe pain associated with the most basic of activities, such as sitting, among other things.

59. As a result of having the Solyx sling implanted in her, Ms. Dolan has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

VII. PLAINTIFF'S RESULTING DAMAGES AND INJURIES

60. Plaintiff suffered serious personal injuries as a direct and proximate result of the Defendants' failure to provide adequate warnings, failure to design, manufacture, sell, or distribute a safe product, and failure to adhere to safe manufacturing processes.

61. As a direct and proximate result of these Defendants' wrongful conduct and the use of Defendants' defective medications, Plaintiff suffered and will continue to suffer from severe injuries and damages, including but not limited to severe personal injuries, great emotional distress, and mental anguish.

62. As a result of use of the Solyx sling as designed, manufactured, promoted, sold and/or supplied by Boston Scientific, and as a result of the negligence, callousness and the other wrongdoing and misconduct of the Defendants as described herein:

a. Plaintiff was injured and suffered injuries to Plaintiff's body and mind, the exact extent of which is not completely known to date;

b. Plaintiff sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

c. Plaintiff incurred medical expenses and will be required to incur additional medical expenses in the future as a result of the injuries and damages Plaintiff suffered;

d. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY

A. Design Defect

63. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

64. Prior to, on, and after the date the Device (the subject Solyx Sling) was implanted in Plaintiff Kerri Dolan and at all relevant times, Defendant designed, distributed, manufactured, sold, and marketed the Device for use in the United States, including Minnesota.

65. At all times herein mentioned, Defendant designed, distributed, manufactured, marketed, and sold the Device such that it was dangerous, unsafe, and defective due to design, manufacture, and lack of adequate warnings.

66. The Device contained all of these defects when it left Defendant's possession.

67. The Pelvic Mesh Product reached Plaintiff Kerri Dolan without substantial change in the condition in which it was sold.

68. The Device had potential risks and side effects that were known or knowable to Defendant by the use of scientific knowledge available before, at, and after the manufacture, distribution, and sale of the Device.

69. Defendant knew or should have known of the defective condition, characteristics, and risks associated with the Device, as previously set forth herein.

70. The Product implanted in Plaintiff Kerri Dolan was not reasonably safe for its intended uses and was defective as described herein with respect to its design. Said design defects include, but are not limited to:

a. The use of polypropylene material in the Device and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Device to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Device, including, but not limited to, the propensity of the Device to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Device which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Device for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

f. The hyper-inflammatory responses to the polypropylene Device leading to problems including chronic pain and fibrotic reaction;

g. The propensity of the polypropylene Device to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

h. The adverse tissue reactions caused by polypropylene Device, which are causally related to infection, as polypropylene is a foreign organic material from animals and/or human cadavers;

i. The harshness of the polypropylene Device upon the female pelvic tissue, and the hardening of the Device in the body;

j. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions, and

k. The use of polypropylene material in the products and the failure to provide adequate directions for use (DFU) and training.

71. At the time Plaintiff Kerri Dolan underwent surgery to have the Solyx sling implanted, technologically feasible alternatives existed.

72. At the time Plaintiff Kerri Dolan underwent surgery to have the Solyx sling implanted, Defendants knew but failed to inform Plaintiff or her implanting physician that the risks of using the device outweighed its benefits.

73. As a direct and proximate result of the Solyx Sling's design defects as described hereinabove, Plaintiff Kerri Dolan has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

74. Thus, Defendant is strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling defective Products.

B. Failure to Warn

75. Prior to, on, and after the date the Device was implanted in Plaintiff Kerri Dolan, and at all relevant times, Defendant designed, tested, distributed, manufactured, advertised, sold, and marketed the Pelvic Mesh Device for use by consumers, such as Plaintiff, in the United States.

76. Prior to, on, and after the date the Device was implanted in Plaintiff Kerri Dolan, Defendant had a duty to exercise due care and avoid unreasonable risk of harm in and about their design, developing, assembling, licensing, labeling, testing, distributing, manufacturing, supplying, ordering, advertising, selling, and marketing of the transvaginal mesh device implanted into the

Plaintiff, including the duty to assure that the product did not pose a significantly increased risk of bodily harm and adverse events.

77. The Device implanted in Kerri Dolan was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendant did not provide sufficient or adequate warnings to Plaintiff's treating physicians regarding, among other subjects:

a. The Device's propensities to contract, retract, and/or shrink inside the body;

b. The Device's propensities for degradation, fragmentation, and disintegration;

c. The rate and manner of mesh erosion or extrusion;

d. The risk of chronic inflammation resulting from the Device;

e. The risk of chronic infections resulting from the Device;

f. The risk of permanent vaginal or pelvic scarring as a result of the Device;

g. The risk of recurrent, intractable, permanent pelvic pain and other pain resulting from the Device;

h. The need for corrective or revision surgery to adjust or remove the Device;

i. The severity of complications that could arise as a result of implantation of the Device;

j. The hazards associated with the Device;

k. The Device's defects described herein;

l. Treatment of stress urinary incontinence with the Device is no more effective than feasible available alternatives;

m. Treatment of stress urinary incontinence with the Device exposes patients to greater risk than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Device makes future surgical repair more difficult than feasible available alternatives;

o. Use of the Device puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

p. Removal of the Device due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

q. Complete removal of the Device may not be possible and may not result in complete resolution of the complications, including pain; and

r. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Device.

78. As a direct and proximate result of the defects herein described, Plaintiff Kerri Dolan has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

VIII. COUNT II: NEGLIGENCE

79. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

80. Prior to, on, and after the date of Plaintiff's implantation with the Device, and at all relevant times, Defendant designed, distributed, manufactured, sold, and marketed the Device for use by consumers such as Plaintiff in the United States.

81. Prior to, on, and after the date of Plaintiff's implantation with the Device, and at all relevant times, Defendant knew or reasonably should have known that the Device and its warnings were dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

82. Prior to, on, and after the date of Plaintiff's implantation with the Device, and at all relevant times, Defendant became aware that the defects of the Device resulted in the Device causing injuries similar to those Plaintiff Kerri Dolan suffered.

83. Prior to and on the date of Plaintiff's implantation with the Device, Defendant breached its duty of care owed to Plaintiff Kerri Dolan and her physicians by its actions and inactions, including but not limited to the following:

a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care to warn Plaintiff's treating physicians about the Device's substantially dangerous condition or about facts making the product likely to be dangerous;

d. Negligently recruiting and training physicians and surgeons to implant its Pelvic Mesh Products and without adequately providing information about the severity frequency and permanency of the risks to those physicians and surgeons;

e. Failing to perform reasonable pre- and post-market testing of the Device to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Device;

g. Advertising, marketing, and recommending the use of the Device, while concealing and failing to disclose or to warn of the dangers known by Defendant to be connected with and inherent in the use of the Device;

h. Representing that the Device was safe for its intended use when, in fact, Defendant knew or should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Device with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations and policy;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Device so as to avoid the risk of serious harm associated with the use of the Device; and

k. Failing to perform adequate evaluation and testing of the Device where such evaluation and testing would have revealed the propensity of the Device to cause injuries as described herein.

84. As a direct and proximate result of Defendant's negligence, as set forth herein, Plaintiff Kerri Dolan has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

IX. COUNT III: BREACH OF EXPRESS WARRANTY

85. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

86. At all material times hereto, Defendant manufactured, distributed, advertised, promoted, and/or sold its pelvic mesh products, including the Device implanted into Plaintiff Kerri Dolan.

87. At all material times hereto, Defendant intended its Device to be used in the manner used by Plaintiff Kerri Dolan.

88. At all material times hereto, Defendant expressly warranted that its Pelvic Mesh Products, including the Device, were safe and fit for use by consumers, that these products were of merchantable quality, that their effects were minimal and comparable to other treatments for SUI and/or POP, and that they were adequately tested and fit for their intended use.

89. At all material times hereto, Defendant was aware that consumers, including Plaintiff Kerri Dolan, would use its Pelvic Mesh Products, including the Device, and accordingly, that Plaintiff Kerri Dolan, was a foreseeable user of its Pelvic Mesh Products.

90. Defendant's Pelvic Mesh Products were expected to reach, and did in fact reach, the ultimate consumer, Plaintiff Kerri Dolan and her implanting physicians, without substantial change in the condition in which they were manufactured and sold by Defendant.

91. Defendant breached express warranties with respect to its Pelvic Mesh Products, including the following:

a. By representing to Plaintiff Kerri Dolan and her healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that its Pelvic Mesh Products, including the Device, were safe, while withholding and concealing information about the substantial risks of serious injury associated with its Pelvic Mesh Products;

b. By representing to Plaintiff Kerri Dolan and her healthcare providers that its Pelvic Mesh Products, including the Device, were as safe, and/or safer than other alternative procedures and devices, while withholding and concealing information that demonstrated its Pelvic Mesh Products were less safe than alternatives available on the market; and

c. By representing to Plaintiff Kerri Dolan and her healthcare providers that its Pelvic Mesh Products, including the Device, were more efficacious than other alternative medications, while withholding and concealing information regarding the true efficacy of its Pelvic Mesh Products.

92. In reliance upon Defendant's express warranties, Plaintiff Kerri Dolan was implanted with Defendant's Device, as prescribed and directed; and, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

93. At the time of making such express warranties, Defendant knew or should have known that its Pelvic Mesh Products did not conform to these express warranties because they were not safe and had numerous serious side effects, many of which Defendant did not accurately warn about, thus making them unreasonably unsafe for their intended purpose.

94. The public, the medical community, Plaintiff Kerri Dolan and her physicians, relied on Defendant's representations and express warranties in connection with the use, recommendation, description, and dispensing of its Pelvic Mesh Products, including the Device implanted into Plaintiff Kerri Dolan.

95. Defendant breached its express warranty to Plaintiff Kerri Dolan in that its Device was not of merchantable quality, safe and fit for its intended use, nor was it adequately tested.

96. The failure of Defendant's Device to be as expressly warranted was a substantial factor in causing Plaintiff Kerri Dolan's injuries as described herein.

97. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff Kerri Dolan has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

X. COUNT IV: LOSS OF CONSORTIUM

98. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

99. Plaintiff Dean Dolan is the spouse of Plaintiff Kerri Dolan, and as a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff Dean Dolan has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

100. As a direct and proximate result of Defendant's conduct as described in this complaint, Plaintiff Dean Dolan has suffered the following injuries and damages:

a. Loss of household services sustained in the past;

b. Loss of household services that, in reasonable probability, Plaintiff Dean Dolan will sustain in the future;

c. Loss of consortium sustained in the past; and

d. Loss of consortium that, in reasonable probability, Plaintiff Dean Dolan will sustain in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for relief and demand judgment against Defendant at trial and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B. For general damages in a sum exceeding this Court's jurisdictional minimum;

C. For specific damages according to proof;

D. For all ascertainable economic and non-economic damages according to proof in a sum exceeding this Court's jurisdictional minimum;

E. For restitution and disgorgement of profits;

F. For punitive and exemplary damages according to proof;

G. For pre-judgment interest and post-judgment interest as allowed by law;

H. For reasonable attorneys' fees;

I. The costs of these proceedings; and

J. For such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues so triable.

Respectfully submitted,

GOLDENBERGLAW, PLLC

Dated: August 21, 2020

By: *s/ Marlene J. Goldenberg*

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